REMARKS

Interview

Applicants thank Examiner Harris for the phone conference on August 3, 2005. During the phone conference, the § 112, second paragraph, §102, and §103 rejections were discussed. Applicants explained that the claims recites the necessary steps under § 112, second paragraph. Applicants also explained that the claims as they stand are not anticipated or rendered obvious by the cited references. Examiner Harris said that she will consider dropping the rejections if we submitted our response in writing providing the necessary explanations of the claimed invention and distinctions over the cited references.

Status of the Claims

Claims 1, 3-23, 25-27, 29, and 31-42 are pending in the current application. Claims 2, 24, 28 and 30 have been canceled without prejudice or disclaimer of the subject matter claimed therein. Claims 25-27 have been amended.

Amendments to the Claims

The amendments to claims 25-27 do not introduce prohibited new matter. Support for the amendment to claims can be found in original claims 25-27.

Rejections of the Claims Under 35 U.S.C. § 112, Second Paragraph

Claims 25-27 and 32-40 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite.

The Office Action asserts that claims 25-27 are vague and indefinite because the claimed methods lack complete steps. Applicants respectfully point out that claims 25-27 as they stand include all the required steps to distinguish the claimed invention from the prior art, which is all that is required (see MPEP 2173.02).

In claims 25 and 26, the first step comprises quantitating the amount of survivin in a sample of urine supernatant from a patient, and the second step comprises comparing the amount of survivin in the sample with that in control samples containing a known quantity of survivin for a specific grade or stage of cancer. Comparing the amount of survivin in the sample with control

sample enables the determination of the specific grade or stage of cancer in the patient. Accordingly, claims 25 and 26 recite a detection step (step 1) and a comparing step (step 2) which correlates the amount of survivin detected in the sample with that of a known sample. Claims 25 and 26 recite a sufficient number of steps and are not indefinite.

Claim 27 is directed to monitoring the progression of cancer. In claim 27, the method involves quantitating the amount of survivin in the sample of urine supernatant and comparing the amount with control samples with known amounts of survivin and known grade of cancer thereby, allowing one to determine the grade of the cancer. The grade of the cancer indicates the progression/regression of the cancer. Thus, measuring the amount of survivin in the urine supernatant of a patient and determining the grade of the cancer is sufficient for monitoring the progression of cancer in a patient. Thus, claim 27 recites the all the required steps for performing the claimed invention.

Further, the claims include the required reagent which is the sample of urine supernatant and control samples with known amount of survivin and known stage/grade of cancer. The claims also require reagents for quantitating the amount of survivin which are described in detail in the specification and include those that interact with survivin such as survivin antibodies and survivin binding partners. On page 4, the Office Action agrees that a method claim need not recite all the technical details taught by the specification or known to one of ordinary skill in the art. The claims only need to recite sufficient information to accurately describe the claimed invention. Thus, Applicants respectfully request withdrawal of the rejection.

Rejections of the Claims Under 35 U.S.C. § 102

A. Claims 1, 3-12, 15-23, 25-27, 29, and 31-42 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 6,656,684 ('684).

Claim 1 and its dependent claims are directed to a method of diagnosing cancer in a patient comprising assaying a sample of urine supernatant for the presence or absence of survivin. The cited U.S. Patent does not disclose a method of diagnosing cancer comprising assaying a sample of urine supernatant for the presence or absence of survivin.

Applicants respectfully point out that a physiological sample of bodily fluid as disclosed in the '684 patent is not urine supernatant as required by the claims. Urine supernatant is distinct

from urine which is a physiological sample of bodily fluid. One would not be able to obtain urine supernatant from a sample of physiological bodily fluid without further treatment of the physiological sample. As acknowledged by the Office Action, one way of isolating urine supernatant from a physiological sample of urine is by centrifugation.

Furthermore, there is no teaching in the cited patent as to assaying urine supernatant for the presence or absence of survivin. A review of the cited U.S. Patent, especially the disclosed Examples, indicates that the cited U.S. Patent relates to detection of survivin from physiological samples, specifically RNA from a tissue sample or physiological bodily fluid. No where does the '684 patent teach the processing of a physiological solution such as urine to produce a supernatant. The claims as they stand are directed to assaying a sample of urine supernatant, not a physiological sample as disclosed in the '684 patent. Accordingly, the cited patent does not anticipate the claimed invention.

Rejections of the Claims Under 35 U.S.C. § 103(a)

A. Claims 1, 3, 4, 6-10, 13-23, 29, 31, 32, 41, and 42 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Jouben-Steele *et al.* in view of Bio-Rad Laboratories Catalog 1998/99.

As acknowledged by the Office Action, Jouben-Steele *et al.* teach assaying urine sediment for the presence of survivin mRNA. Jouben-Steele *et al.* do not disclose assaying a sample of urine supernatant for the presence or absence of survivin for diagnosing, prognosing, or monitoring cancer in a patient. Likewise, the cited catalog of Bio-Rad Laboratories does not teach assaying a sample of urine supernatant for the absence or presence of survivin for diagnosing cancer, and the cited catalog does not make up the deficiencies of Jouben-Steele. Neither of the cited references discloses the presence of survivin in urine supernatant and neither of the cited references teaches the presence or absence of survivin in urine supernatant is associated with cancer. One would not have reasonably expected to obtain the claimed invention by combining the two references. Accordingly, the cited references do not render the claimed invention obvious.

B. Claims 1, 3-13, 15-23, 25-27, 29, and 31-42 are rejected under 35 U.S.C. § 103(a) as

being unpatentable over Jouben Steele *et al.* in view of U.S. Patent 6,656,684.

The deficiencies of Jouben-Steele *et al.* have been discussed above. Jouben-Steele *et al.* do not disclose assaying a sample of urine supernatant for the absence or presence of survivin for diagnosing, prognosing, or monitoring cancer in a patient.

The cited U.S. Patent does not disclose a method of diagnosing cancer comprising assaying a sample of urine supernatant for the presence or absence of survivin. In contrast to the claimed methods of the present application, the cited U.S. Patent teaches the detection of survivin from physiological samples. The physiological sample of bodily fluid as disclosed in the '684 patent is not urine supernatant as required by the claims.

Neither of the cited references discloses assaying a sample of urine supernatant for the presence or absence of survivin for diagnosing, prognosing, or monitoring cancer in a patient. One would not have reasonably expected to obtain the claimed invention by combining the two cited references. Accordingly, the cited references do not render the claimed invention obvious.

C. Claims 1, 3-23, 25-27, 29, and 31-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,656,684 in view of Bio-Rad Laboratories Catalog 1998/99.

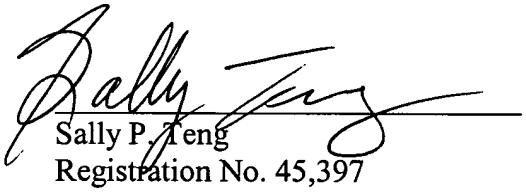
The deficiencies of the cited U.S. Patent and the Bio-Rad Laboratories Catalog have been discussed above. Neither of them discloses assaying a sample of urine supernatant for the presence or absence of survivin for diagnosing, prognosing, or monitoring cancer in a patient. One would not have reasonably expected to obtain the claimed invention by combining the two cited references. Accordingly, the cited references do not render the claimed invention obvious.

Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request entry of the amendments, reconsideration, and the timely allowance of the pending claims. A favorable action is awaited. Should the Examiner find that an interview would be helpful to further prosecution of this application, they are invited to telephone the undersigned at their convenience.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,
Morgan, Lewis & Bockius LLP



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